UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,438	01/05/2004	Wolfgang Fitz	2960/118	3735
	7590 06/19/200 & SUNSTEIN LLP	8	EXAMINER	
125 SUMMER	STREET		STEWART, JASON-DENNIS NEILKEN	
BOSTON, MA 02110-1618			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			06/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary		Application No.	Applicant(s)				
		10/752,438	FITZ ET AL.				
		Examiner	Art Unit				
		JASON-DENNIS STEWART	3738				
Period fo	The MAILING DATE of this communication ap or Reply	ppears on the cover sheet with the	correspondence address				
WHIC - Exter after - If NC - Failu Any (	ORTENED STATUTORY PERIOD FOR REPICHEVER IS LONGER, FROM THE MAILING Insions of time may be available under the provisions of 37 CFR 1 SIX (6) MONTHS from the mailing date of this communication. Poeriod for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by staturely received by the Office later than three months after the mailing datent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATIO .136(a). In no event, however, may a reply be to d will apply and will expire SIX (6) MONTHS fron the, cause the application to become ABANDON	N. imely filed in the mailing date of this communication. ED (35 U.S.C. § 133).				
Status							
1)[\	Responsive to communication(s) filed on 06	March 2008					
•	Responsive to communication(s) filed on <u>06 March 2008</u> .  This action is <b>FINAL</b> .  2b) This action is non-final.						
3)	<i>/</i>						
٥/١	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
•		dication					
	Claim(s) <u>1 and 3-46</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.						
		awii iioiii consideration.					
,	Claim(s) is/are allowed.						
	Claim(s) <u>1 and 3-46</u> is/are rejected.						
	Claim(s) is/are objected to.						
8)[_]	Claim(s) are subject to restriction and/	or election requirement.					
Applicati	on Papers						
9)	The specification is objected to by the Examir	ner.					
10)	The drawing(s) filed on is/are: a)□ ac	cepted or b) objected to by the	Examiner.				
	Applicant may not request that any objection to the	e drawing(s) be held in abeyance. Se	ee 37 CFR 1.85(a).				
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority ι	ınder 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
2)  Notic 3)  Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date See Continuation Sheet.	4) Interview Summar Paper No(s)/Mail I 5) Notice of Informal 6) Other:	Date				

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 09 November 2007, 14 January 2008, 06 March 2008, 30 May 2008.

Application/Control Number: 10/752,438 Page 2

Art Unit: 3738

## **DETAILED ACTION**

The following is a Final Office action in response to communications received on 03/06/2008. Claims 1, 12, 15-18, and 27 have been amended. Claim 2 has been cancelled. Claims 28-46 have been added. Therefore, Claims 1 and 3-46 are pending and addressed below.

# Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 32 and 33 are dependent on themselves which is improper and thus all claims depending from theses claims lack antecedent basis. Appropriate correction is requested.

## Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Application/Control Number: 10/752,438 Page 3

Art Unit: 3738

4. Claims 1, 12-14, 16-18, 26, 28-31, 39-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckhoff 5,681,354.

5. Eckhoff discloses an implant for implantation on the femoral condyle that has a joint facing surface and a bone facing surface. The implant opposes both a portion of the condyle and the trochlea (Fig. 1) and also has a surface cut and a constant thickness over the implant (Fig. 2). Eckhoff further discloses a plurality of symmetrical pins 11 for attachment to the bone surface. The shape of the implant substantially matches the articulating surfaces of the distal femur on the bone facing side and proximal tibia or proximal tibial implant of the joint facing side (Fig. 1).

### Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 3-5, 8, 9, 11, 19-25, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckhoff 5,681,354 in view of Fell 2003/0055501.

Eckhoff discloses the invention as claimed and as discussed above. However, although implied, Eckhoff does not disclose a specific thickness of the implant.

Eckhoff discloses a metal implant (paragraph 14) that comprises biologically active materials (paragraph 72) used to correct cartilage defects in the knee joint and discloses the implant will be the thickness of the defect and could also have varying

thickness depending on cartilage wear (paragraphs 17, 54). The device is implanted via a 3cm-5cm incision. Fell also discloses the joint being restored to full extension and 120 degrees of flexion. Fell further discloses that the implant is selected from a library of implants as well (paragraph 25, 95).

It would have been obvious to one of ordinary skill in the art to use the thickness, coating, and incision of Fell with the device of Eckhoff in order to effectively replace worn articular cartilage, restore normal joint alignment, as taught by Fell (paragraph 25).

8. Claims 6, 7, 10, and 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckhoff 5,681,354 in view of Fell 2003/0060882.

Eckhoff discloses the invention as claimed and as discussed above. However, Eckhoff does not disclose an offset thickness.

Fell '882 discloses a metal knee prosthesis (paragraph 74) with biologically active surfaces and an offset defined by a ratio (paragraph 28, fig. 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Eckhoff with the offset of Fell '882 in order to restore normal joint alignment without requiring any bone resection as taught by Fell '882 (paragraph 17).

9. Claims 15 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckhoff 5,681,354 in view of Rolston 2004/016730.

Eckhoff discloses the invention as claimed and as discussed above. However, Eckhoff does not disclose a second implant component that covers a portion of the patellar surface. Rolston discloses a second component 58 that has a first surface that engages the femur mating surface of the patella and a second surface that engages the

patella (fig. 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Eckhoff with the patellar implant of Rolston in order to remedy a patella that is also diseased as taught by Rolston (paragraph 5).

### Response to Arguments

10. Applicant's arguments with respect to claims 1 and 3-27 have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

- 11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Eckhoff 5,728,162 is added as a reference because it discloses an implant used to resurface both femoral condyles.
- 12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3738

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS /Jason-Dennis Stewart/ Examiner, Art Unit 3738

/Brian E Pellegrino/ Primary Examiner, Art Unit 3738